DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 8, 2015

TORNIER SAS
Mr. Aymen Azaiez
Regulatory Affairs Specialist
161 Rue Lavoisier
38330 Montbonnot Saint Martin
France

Re: K143374
Trade/Device Name: BLUEPRINT Patient Specific Instrumentation
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS
Dated: March 3, 2015
Received: March 9, 2015

Dear Mr. Azaiez:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K143374

Device Name
BLUEPRINT Patient Specific Instrumentation

Indications for Use *(Describe)*
The hardware
The Aequalis Glenoid Guides are patient-specific drill guides. They have been specially designed to assist in the intraoperative positioning of glenoid components used with total anatomic shoulder arthroplasty procedures using anatomic landmarks that are identifiable on patient-specific preoperative CT-scans.

Aequalis PerFORM Anatomic Glenoid Guide is used by surgeons to facilitate the placement of the Aequalis PerFORM glenoids.

The software

The BLUEPRINT 3D planning software is a medical device for surgeon composed of one software component. It is intended to be used as a pre-surgical planner for shoulder orthopedic surgery.

BLUEPRINT 3D planning software runs on standard personal and business computers running Microsoft Windows or Mac OS operating systems.

The software supports DICOM standard to import the CT-Scan (Computed Tomography) images of the patient. Only CT-Scan modality can be loaded with BLUEPRINT3D planning software.

BLUEPRINT 3D planning software allows surgeon to visualize, measure, reconstruct, and annotate anatomic data. It allows surgeon to design patient specific guides based on the presurgical plan.

This device is intended for use provided anatomic reference points necessary for positioning of the guide are present on the CT scan.

The software leads to the generation of a surgery report along with a 3D file of the patient-specific guide.

BLUEPRINT 3D planning software does not include any system to manufacture the guide.

BLUEPRINT 3D planning software is to be used for adult patients only and should not be used for Diagnostic purpose.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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Summary of Safety and Effectiveness information
Traditional 510(k) Premarket – BLUEPRINT™ Patient Specific Instrumentation (K143374)

1) Device name

Trade name: BLUEPRINT™ Patient Specific Instrumentation

Common name: Patient Specific Instrument

Classification name: Prosthesis, Shoulder, Semi-constrained, Metal/Polymer Cemented (§888.3660)

2) Submitter :

TORNIER SAS
161 rue Lavoisier
38330 Montbonnot Saint Martin- France
Registration Number: 3000931034

3) Company contact :

Tornier SAS
Mr Aymen AZAIEZ
Regulatory Affairs Specialist
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e-mail : aymen.azaiez@tornier.com

4) Classification

Device class: Class II
Classification panel: Orthopedic
Product code: KWS,

5) Equivalent / Predicate device :

CAS PSI Shoulder, Zimmer CAS (K131129)
SurgiCase Orthopaedics, SurgiCase Connect, SurgiCase Guides, Materialise N.V. (K112389)
Signature Personalized Patient Care System - Glenoid Guide System, Biomet Manufacturing Corp (K130126)
Match Point System, Match Point System Guide, SurgiCase Connect, Materialise N.V. (K131559).
Aequalis PerFORM glenoid System, TORNIER SAS (K111902)
OsiriX MD, Pixmeo, SARL (K101342)

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6) Device description :

BLUEPRINT™ Patient Specific Instrumentation is composed of two components: *Aequalis Glenoid Guides (hardware) and BLUEPRINT 3D planning software (software).*

BLUEPRINT™ Patient Specific Instrumentation is the responsibility of Tornier including the *Aequalis Glenoid Guides* and *BLUEPRINT 3D planning software*. Tornier is the legal manufacturer for the hardware and the software.

The hardware

The *Aequalis Glenoid Guides* are patient-specific instruments specially designed to facilitate the implantation of the Aequalis PerFORM shoulder prostheses and are exclusively reserved for this use.

The *Aequalis Glenoid Guides* are designed and manufactured based on a pre-operative plan generated only by the software *BLUEPRINT™ 3D planning software*.

The software

BluePrint 3D Planning software is composed of one software component connected to an Online Management System (OMS). The software installed on a computer is intended to be used by orthopedic surgeons, as a preoperative planning software for shoulder arthroplasty surgery (= total anatomic shoulder replacement).

It is intended to help to plan an operation by allowing surgeons to:

- position and to select the glenoid implant,
- design a patient specific pin guide.

Intended Use

The hardware

The Aequalis Glenoid Guides are intended to be used as surgical instruments to assist in the intraoperative positioning of glenoid components used with total anatomic shoulder arthroplasty procedures using anatomic landmarks that are identifiable on patient-specific preoperative CT-scans.

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The software

The *BLUEPRINT 3D planning software* is intended to be used as a medical software to assist in pre-operative surgical planning for shoulder surgery.

7) Materials :

The *Aequalis Glenoid Guides are* manufactured from polyamide 2200 medical grade.

8) Indications :

The hardware

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S.A.S. au capital de 35 043 008 €
SIRET : 070 501 275 000 21
R.C.S. : 070 501 275
CODE APE : 3250 A

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9) Summary of technological characteristics

Table 1: Main features comparison

Main features or system characteristics	***BLUEPRINT™ Patient Specific Instrumentation***	**CAS PSI Shoulder Guide (K131129)**	**SurgiCase Guides (K112389)**	**Signature Personalized Patient Care System - Glenoid Guide System (K130126)**	**Match Point System Guide (K131559)**	**Aequalis PerFORM glenoid System (K111902)**	**OsiriX MD (K101342)**
Material	Polyamide 2200	Polyamide	Polyamide 2200	Plastic	Polyamide 2200	UHMWPE + CoCr	NA
Standard	USP Class VI compatible	Unknown	USP Class VI compatible	Unknown	USP Class VI compatible	ISO 5834-2 ISO 5832-7	NA
Product Code	KWS	KWS, PBF	PBF	KWS, KWT, PAO-, and MBF	KWS	KWS	LLZ
Surgical procedure	Total anatomic shoulder arthroplasty	Reversed shoulder arthroplasty	Upper extremities	Total and reverse shoulder arthroplasty	Total and reverse shoulder arthroplasty	Anatomic shoulder arthroplasty	Mammography
Single-use	Yes	Yes	Yes	Yes	Yes	Yes	NA
Sterile	No	No	No	No	No	Yes	NA
Manufacturer	Tornier SAS	Zimmer	Materialise N.V.	Biomet	Materialise N.V.	Tornier SAS	Pixmeo, SARL

Device comparison showed that the proposed device is substantially equivalent in intended use, materials and performance characteristics to the predicate devices.

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10) Non-clinical testing

BLUEPRINT™ Patient Specific Instrumentation was validated through non-clinical studies performed on cadaveric specimen or performed by using patients' data:

Validation and / or Verification Method	Acceptance Criteria description	Verification and Validation Results
Seating validation Test	The seating offset between reference method and the software calculation should be compliant	Acceptable
Reaming validation Test	The Reaming offset between reference method and the software calculation should be compliant	Acceptable
Orientation and Direction angles Validation Test	The orientation angle offset and the Humeral Head Subluxation direction offset between reference method and the software calculation should be compliant	Acceptable
Glenoid Version and Inclination angle validation test	The version angle offset between reference method and the software calculation should be compliant A concordance correlation coefficient ρ between the reference method and the software calculation of the inclination should be compliant	Acceptable
Humeral Head subluxation and direction measure	The Humeral Head Subluxation offset and the Humeral Head Subluxation direction offset between reference method and the software calculation should be compliant	Acceptable
Patient Specific Guiding Wire test	Version angle error, inclination angle error and entry point error should be compliant	Acceptable
Segmentation Accuracy Test	Mean Distance Error in the surgical zone between 3D reconstruction and the reference reconstruction should be compliant	Acceptable
Clinical Case Series	Pre-operative Plan compared to post-operative implant position	Acceptable

This testing aims to validate the procedure of generating a patient specific guide matching the patient anatomy according to software measures and preoperative planning (implant positioning).

Non clinical testing was performed on *BLUEPRINT™ Patient Specific Instrumentation* to assess the performance of the device and to demonstrate substantial equivalence to the predicate devices. No safety or efficacy issues were raised with this device based on the testing.

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11) Substantial equivalence conclusion

Based upon this comparative study, substantial equivalence of *BLUEPRINT™ Patient Specific Instrumentation* to the predicates can be demonstrated on the following grounds, according to the FDA's Guidelines for Substantial Equivalence Decision making Process:

- *BLUEPRINT™ Patient Specific Instrumentation* is compared to the predicate devices.
- *BLUEPRINT™ Patient Specific Instrumentation* has the same intended use as predicate devices: CAS PSI Shoulder, SurgiCase Guides, Signature Personalized Patient Care System - Glenoid Guide System, Match Point System Guide.
- *BLUEPRINT 3D planning software* comparison analysis showed that the proposed substantially equivalent to similar features of automatic segmentation to predicate device Osirix.
- *BLUEPRINT 3D planning software* user manual is similar in indications precautions, warnings, and instructions as the predicate devices: CAS PSI Shoulder, SurgiCase Guides, Signature Personalized.

- Major technological characteristics are equivalent between *BLUEPRINT™ Patient Specific Instrumentation* and the predicate devices:
    - Equivalence of general features
    - Equivalent surgical procedures
    - Equivalent materials
    - Equivalent intended use, indications for use

Therefore, in the light of the above information, the *BLUEPRINT™ Patient Specific Instrumentation* is found to be equivalent to the predicate devices.

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